

## UNITED STATES PATENT AND TRADEMARK OFFICE

In re AstraZeneca UK Limited  
Request for Patent Term Extension  
U.S. Patent No. 4,659,516


:  
: **ORDER GRANTING**  
: **INTERIM EXTENSION**

On June 24, 2002, AstraZeneca UK Limited, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,659,516, filed an application under 35 U.S.C. § 156, requesting an extension of 1,165 days. The original expiration date of the patent is October 1, 2004. The term of the patent has been previously extended to October 1, 2005. The patent claims the active ingredient fulvestrant in the human drug product "FASLODEX®." The application indicates, and the Food and Drug Administration (FDA) has confirmed, that the product has undergone a regulatory review under Section 505 or 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product. FDA's determination of the regulatory review period of this product is not yet final.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,659,516 is granted for an additional period of one year from the extended expiration date of the patent, until October 1, 2006.

12/1/05  
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Date

  
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Jon W. Dudas  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office